

Message

From: Norris, Anne [Anne.Norris@fda.hhs.gov]
Sent: 10/4/2017 1:16:10 PM
To: Strauss, Linda [Strauss.Linda@epa.gov]; McNally, Robert [McNally.Robert@epa.gov]; StClair, Christie [StClair.Christie@epa.gov]; Valentine, Julia [Valentine.Julia@epa.gov]; Daguillard, Robert [Daguillard.Robert@epa.gov]; Putnam, Juli [JuliAnn.Putnam@fda.hhs.gov]; Dooren, Jennifer [Jennifer.Dooren@fda.hhs.gov]; DeLancey, Siobhan [Siobhan.Delancey@fda.hhs.gov]; Zborowsky, Ashley [Ashley.Zborowsky@fda.hhs.gov]
CC: Nalubola, Ritu [Ritu.Nalubola@fda.hhs.gov]; Flamm, Eric [Eric.Flamm@fda.hhs.gov]; Epstein, Laura [Laura.Epstein@fda.hhs.gov]; Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
Subject: RE: GE Mosquito Final Guidance Announcement

Good morning,

Links to the final documents are below.

CVM Update: [FDA Issues Final Guidance Clarifying FDA and EPA Jurisdiction over Mosquito-Related Products](#)
Final Guidance: [Guidance for Industry #236 – Clarification of FDA and EPA Jurisdiction over Mosquito-Related Products](#)
Federal Register Notice: [Guidance: Clarification of the Food and Drug Administration and Environmental Protection Agency Jurisdiction Over Mosquito-Related Products](#)

Could you please share your final QAs when they're ready and a link to what EPA posts?

Also, who is the primary press officer handling this today?

Thanks,
Anne

From: Strauss, Linda [mailto:Strauss.Linda@epa.gov]
Sent: Tuesday, October 03, 2017 5:50 PM
To: Norris, Anne; McNally, Robert; StClair, Christie; Valentine, Julia; Daguillard, Robert; Putnam, Juli; Dooren, Jennifer; DeLancey, Siobhan; Zborowsky, Ashley
Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura; Milewski, Elizabeth; Mendelsohn, Mike
Subject: RE: GE Mosquito Final Guidance Announcement

Good. Will likely have to send revised set of EPA Q's and A's in the a.m.

Thanks, Linda

From: Norris, Anne [mailto:Anne.Norris@fda.hhs.gov]
Sent: Tuesday, October 03, 2017 5:29 PM
To: Strauss, Linda <Strauss.Linda@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; StClair, Christie <StClair.Christie@epa.gov>; Valentine, Julia <Valentine.Julia@epa.gov>; Daguillard, Robert <Daguillard.Robert@epa.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Zborowsky, Ashley <Ashley.Zborowsky@fda.hhs.gov>
Cc: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Flamm, Eric <Eric.Flamm@fda.hhs.gov>; Epstein, Laura <Laura.Epstein@fda.hhs.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: GE Mosquito Final Guidance Announcement

Hi Linda,

How are things progressing with finalizing EPA's QAs? Do you need anything else from FDA?

Tomorrow morning, we'll be giving Oxitec, Intrexon, and the Hill a heads up about half an hour before the announcement goes public, then we'll notify some key partners (BWG, Health Canada, FAS). The FR notice will display at 8:45 a.m. and we will post the final guidance and CVM Update shortly thereafter. We'll send you links when they're live.

Please call me if you need anything!

Anne

From: Strauss, Linda [<mailto:Strauss.Linda@epa.gov>]

Sent: Tuesday, October 03, 2017 10:17 AM

To: Norris, Anne; McNally, Robert; StClair, Christie; Valentine, Julia; Daguiard, Robert; Putnam, Juli; Dooren, Jennifer; DeLancey, Siobhan; Zborowsky, Ashley

Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura; Milewski, Elizabeth; Mendelsohn, Mike

Subject: RE: GE Mosquito Final Guidance Announcement

Thanks, will do.

From: Norris, Anne [<mailto:Anne.Norris@fda.hhs.gov>]

Sent: Tuesday, October 03, 2017 9:58 AM

To: McNally, Robert <McNally.Robert@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>; StClair, Christie <StClair.Christie@epa.gov>; Valentine, Julia <Valentine.Julia@epa.gov>; Daguiard, Robert <Daguiard.Robert@epa.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Zborowsky, Ashley <Ashley.Zborowsky@fda.hhs.gov>

Cc: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Flamm, Eric <Eric.Flamm@fda.hhs.gov>; Epstein, Laura <Laura.Epstein@fda.hhs.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>

Subject: RE: GE Mosquito Final Guidance Announcement

Hi Linda,

Attached are FDA's comments/edits on the EPA Q&A document you shared last night. We appreciate the opportunity to review! The legal counsel and subject matter experts who had comments/edits are copied on this email, so please let us know if you have questions or concerns after checking with EPA's experts.

When you have finalized, could you please share the version you plan to use?

Thanks,

Anne

From: Norris, Anne

Sent: Monday, October 02, 2017 7:00 PM

To: 'McNally, Robert'; Strauss, Linda; StClair, Christie; Valentine, Julia; Daguiard, Robert; Putnam, Juli; Dooren, Jennifer

Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura; Milewski, Elizabeth; Mendelsohn, Mike

Subject: RE: GE Mosquito Final Guidance Announcement

Here you go.

From: McNally, Robert [<mailto:McNally.Robert@epa.gov>]

Sent: Monday, October 02, 2017 5:59 PM

To: Norris, Anne; Strauss, Linda; StClair, Christie; Valentine, Julia; Daguillard, Robert; Putnam, Juli; Dooren, Jennifer
Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura; Milewski, Elizabeth; Mendelsohn, Mike
Subject: RE: GE Mosquito Final Guidance Announcement
Importance: High

Can you send the final version of the FR that will display Weds?

Thanks

Bob

From: Norris, Anne [<mailto:Anne.Norris@fda.hhs.gov>]
Sent: Monday, October 02, 2017 5:12 PM
To: Strauss, Linda <Strauss.Linda@epa.gov>; StClair, Christie <StClair.Christie@epa.gov>; Valentine, Julia <Valentine.Julia@epa.gov>; Daguillard, Robert <Daguillard.Robert@epa.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Cc: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Flamm, Eric <Eric.Flamm@fda.hhs.gov>; Epstein, Laura <Laura.Epstein@fda.hhs.gov>; McNally, Robert <McNally.Robert@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: GE Mosquito Final Guidance Announcement

Hi Linda,

Thanks for sharing EPA's Q&As. We're reviewing them now and will be in touch with feedback tomorrow. At this point we think the announcement will almost certainly happen Wednesday morning. The FR notice is scheduled to display at 8:45 a.m.

One note on the FDA QA that you edited on Friday – by removing the Oxitec mention in the first sentence, it now reads as though EPA would regulate all GE mosquitoes, which is not the case. Made a small edit in blue to the response below to indicate that EPA will regulate GE mosquitoes that are intended for population control purposes.

Please let us know if you have any questions or concerns. We'll be in touch tomorrow to finalize plans.

Thanks again,
Anne

From: Norris, Anne
Sent: Friday, September 29, 2017 4:52 PM
To: 'Strauss, Linda'; StClair, Christie; Valentine, Julia; Daguillard, Robert; Putnam, Juli; Dooren, Jennifer
Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura; McNally, Robert; Milewski, Elizabeth; Mendelsohn, Mike
Subject: RE: GE Mosquito Final Guidance Announcement

Thank you, Linda!

Anne

From: Strauss, Linda [<mailto:Strauss.Linda@epa.gov>]
Sent: Friday, September 29, 2017 4:31 PM
To: Norris, Anne; StClair, Christie; Valentine, Julia; Daguillard, Robert; Putnam, Juli; Dooren, Jennifer
Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura; McNally, Robert; Milewski, Elizabeth; Mendelsohn, Mike
Subject: RE: GE Mosquito Final Guidance Announcement

Hi Anne, we'll likely be getting our Q/A's to you Monday am. and not today. Also, you asked us to expand on this FDA Q/A. See below. Our General Counsel suggests deleting mention of a specific product so we made that change too.

Ex. 5 - Deliberative Process

From: Norris, Anne [<mailto:Anne.Norris@fda.hhs.gov>]

Sent: Friday, September 29, 2017 12:23 PM

To: Strauss, Linda <Strauss.Linda@epa.gov>; StClair, Christie <StClair.Christie@epa.gov>; Valentine, Julia <Valentine.Julia@epa.gov>; Daguillard, Robert <Daguillard.Robert@epa.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>

Cc: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Flamm, Eric <Eric.Flamm@fda.hhs.gov>; Epstein, Laura <Laura.Epstein@fda.hhs.gov>; McNally, Robert <McNally.Robert@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>

Subject: RE: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

Hi EPA,

Attached are our CVM Update and Responsive QAs for the GE mosquito final guidance for your awareness. They have received legal clearance from our Office of the Chief Counsel. The responsive QAs in red are new additions to our list of questions since we shared with you in January for the draft guidance, but many of the questions you saw in January now have modified responses to reflect current circumstances.

The exact timing of the announcement is still being determined and we will keep you posted. When you have developed your listserv and QAs, could you please share with us for awareness?

Please let us know if you have any questions or concerns.

Thanks!
Anne

From: Norris, Anne

Sent: Thursday, September 28, 2017 2:13 PM

To: 'Strauss, Linda'; 'StClair, Christie'; 'Valentine, Julia'; 'Daguillard, Robert'; Putnam, Juli

Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura; 'McNally.Robert@epa.gov'; 'Milewski, Elizabeth'; 'Mendelsohn, Mike'

Subject: RE: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

Good afternoon,

We just received confirmation that this announcement will not be happening until early next week. We're awaiting precise timing, but wanted to let you know that the guidance is not going out tomorrow as originally anticipated.

Will be in touch when we know more, but hope to have the CVM Update to you very soon and the responsive QAs should follow shortly after that.

Thanks,
Anne

From: Norris, Anne
Sent: Wednesday, September 27, 2017 5:46 PM
To: 'Strauss, Linda'; 'StClair, Christie'; 'Valentine, Julia'; 'Daguillard, Robert'; Putnam, Juli
Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura; 'Mcnally.Robert@epa.gov'; 'Milewski, Elizabeth'; 'Mendelsohn, Mike'
Subject: RE: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

To recap status for everyone: Linda will be in the office Thursday and Friday and she's steering the ship for EPA communications. The EPA team is working on responses to anticipated questions from press and stakeholders. FDA will share our comms tomorrow as soon as we are able.

If you have any questions or concerns, please let us know.

Thanks,
Anne

From: Norris, Anne
Sent: Wednesday, September 27, 2017 5:02 PM
To: 'Strauss, Linda'; 'StClair, Christie'; 'Valentine, Julia'; 'Daguillard, Robert'; Putnam, Juli
Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura; 'Mcnally.Robert@epa.gov'; Milewski, Elizabeth; Mendelsohn, Mike
Subject: RE: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

Looping in Bob, Elizabeth, and Mike now because I tried calling all four of the EPA communications contacts we have on this issue and can't reach anyone. Normally, I'd wait until the morning and try again, but given the time constraints, we just need to ensure that someone from EPA communications is handling this. Linda's voicemail said Ex. 6 - Personal Privacy

Ex. 6 - Personal Privacy so hoping that if she's already Ex. 6 - Personal Privacy that you may be able to suggest who else we can contact.

Thanks,
Anne

From: Norris, Anne
Sent: Wednesday, September 27, 2017 4:42 PM
To: Strauss, Linda; StClair, Christie; Valentine, Julia; 'Daguillard, Robert'; Putnam, Juli
Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura
Subject: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK
Importance: High

Hi Linda,

We just learned that this final guidance is on an EXTREMELY fast trajectory and we're almost certainly going to be announcing by this Friday (9/29). Unfortunately, our communications documents are still in clearance and it would be premature to send them to you in case edits still need to be made. At this point, we should be able to share tomorrow, but it's unclear at what time.

We will share our CVM Update and Responsive QAs at the earliest point possible; however, if you wait until after you view our comms to start developing your QAs or talking points, you won't be allowing yourselves adequate time.

Additionally, our responsive QAs are primarily geared toward addressing the questions that the FDA anticipates getting, which won't be very helpful for EPA's needs when it comes to questions that will be directed to EPA from media and stakeholders. Of particular sensitivity right now is the issue of mosquitoes and hurricane relief.

Given the short timeframe, we would strongly suggest that you and your team consult with the EPA policy team working on this issue to get their thoughts on what issues/questions they expect to arise and how they would advise you to handle them. My understanding is that those people are Bob McNally, Elizabeth Milewski, and Mike Mendelsohn.

As Juli had previously mentioned, some examples of the types of questions you might get could be things like:

- What further regulation will the sponsor have to go through to conduct field trials in jurisdictions within the US or to get a commercial approval for the mosquitoes? Will EPA rely on the data the sponsor already provided to the FDA? How long will the process take?
- Do you have any applications/permits/whatever the correct terminology is from Oxitec in house that you are currently reviewing?
- Does the EPA have comment on FDA's guidance? Will this delay the approval/permitting of Oxitec's GE mosquitoes to Hurricane-stricken areas?

Please keep in touch with questions and concerns – feel free to call me anytime at 240-402-0132. We'll reach out tomorrow about the status of our communications and to set up a call with you, if needed.

Thanks,
Anne

Anne Norris
Health Communications Specialist

Strategic Communications & Public Engagement Team
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U.S. Food & Drug Administration
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